Speech by Cong. Henry A. Waxman
At the 3rd Annual Pharmaceutical Marketing Congress
September 28, 2004

Introduction; Medicare benefit on the horizon:

It's a pleasure to join you all here today. This is obviously a very large and well-attended conference, and—I'll be frank—attended by a part of the pharmaceutical industry that is not commonly the part I deal with. But what you do to market your drugs, and how you do it, is a critical element in how the industry is perceived, so I'm glad to have the opportunity to share some of my thoughts with you.

We stand at the brink of what can potentially be the largest single increase in prescription drug coverage in history. The addition of prescription drug coverage to Medicare has been a goal of Medicare's supporters for well over a quarter of a century.

And yet, the likelihood that this expansion will result in more unhappiness and disappointment than celebration of the successful addition of a critical Medicare benefit is high.

I believe there are critical flaws in the design of the drug benefit being made available to Medicare beneficiaries. And I believe that the way it will be made available—through single-benefit prescription drug private insurance plans—will inevitably mean serious problems for the Medicare beneficiary.

As individual insurers design—and change—their benefits, additional unhappiness with the program is likely to increase.

And because the standard drug benefit fails to provide comprehensive coverage and requires large out-of-pocket spending, there's even more possibility for disappointment when beneficiaries see the specifics.

So the idea that Medicare beneficiaries will stop worrying about the cost of prescription drugs once they get coverage is not going to occur.

All of these kinds of issues may not be the direct responsibility of the drug companies. But I believe they will add to a general feeling now prevalent in this country of distrust and unhappiness with the pharmaceutical industry.

And that is a result which should be of great concern to all of you.

Pharmaceutical industry's public standing:

Let's step back and look at the issue I was asked to talk with you about today: the pharmaceutical industry's public standing.

I'll be blunt: it's bad.

This is an industry with a great deal of political power. There is no doubt about that. But in spite of that—or maybe even because of that—it is an industry viewed with a great deal of suspicion, and indeed bad feeling by much of the American public.

This is a situation that should bring a lot soul searching to those of you in the industry.

In some sense it is stunning that an industry that clearly has made such significant contributions to the development of medical care in this country should find itself so reviled. After all, this is an industry that without question has brought us truly miracle drugs that have resulted in treatment and cures undreamed of only a few decades ago. This is an industry that has achieved such significant progress that its product is seen as an absolutely essential part of good medical treatment.

So how did we get to this situation? And what can be done to change it? I'd like to give you my thoughts about both of those questions.

Why is the standing of the industry so low:

Let me just suggest several different things that are all relevant to the overall picture. Some of them have had more effect than others, but in my view all of them are contributing factors.

Success increases expectations:
First, in some sense, the very success of the industry in developing miracle drugs and in seeing drugs become so integral to health care treatment has meant an increase in expectations. Once those drugs are available, people understandably think they should have them. The result is a great deal of unhappiness when those treatments are so expensive, they are often beyond the means of people to pay to get them.

Americans don't understand why medicines are so expensive. But what is really critical here is that they certainly don't understand why they pay more for the very same drug than people pay across the border in Canada or Mexico.

Discrimination in pricing:
They understand a very basic point: they are being discriminated against in the prices they are required to pay.

I know—and perhaps some of them know as well—the arguments the industry makes that somehow this is necessary to support research activities that make these drugs

available in the first place. But that argument doesn't make sense to the average citizen, and frankly it doesn't make much sense to me either.

So people are unhappy that their drugs cost a lot. They are unhappy that prescription drugs increase in cost faster than their paycheck or their Social Security check increases. Most of all they are unhappy and suspicious of those costs when they find out people pay less for the very same drug in other countries.

The push to allow reimportation of drugs from other countries is a direct offshoot of that frustration.

Additionally, there are still many Americans who pay for their drug costs out of pocket. Seniors are traditionally one of groups, but there are many others. 45 million uninsured Americans obviously don't have drug coverage. But even many people with insurance don't have drug coverage.

That means that when they are faced with the highest prices for drugs, they bear the full brunt of the economic burden. It is not surprising that they are keenly aware that they are paying higher prices than their neighbor who is lucky enough to be insured.

Discounts:
So that takes us to point number two: the industry defends itself by saying it provides major discounts or rebates to certain purchasers, so a lot of people are actually paying lower prices than it appears.

Well, that argument might make sense to economists, but people without insurance can't help but think that if there is enough room in the price to discount it for some people, maybe it would be fairer to charge them less.

Whatever the merits of that argument, what we do know is that the way the system works now leaves the most vulnerable facing the highest prices.

Research issue:
Next, let's look at the famous argument about how these high prices are necessary or research into new drugs would be severely affected. Certainly that argument gives people pause, because none of us wants to stop research into truly innovative drugs.

But when people see that drug companies spend more on marketing than they do on research, they aren't quite so impressed by the argument that it is research costs that make those high prices necessary.

When profits exceed research budgets, and the profits of the drug companies are among the highest of any industry, they think maybe those profits explain the high prices more than the research budget does.

Then there is the argument about research itself. Too often, the research dollars of companies go into developing the so-called me-too drugs rather than actually financing breakthrough drugs.

More than one critic of the industry has pointed out that much of the basic research leading to breakthrough drugs has come from publicly-sponsored research in universities or research done at NIH.

Companies benefit from that certainly, and they also clearly perform a necessary and important role of testing, manufacturing and marketing the drug. Nonetheless, frequently the source of financing for the innovation was the public purse.

Then the public pays again in the form of exceedingly high prices. That's a pretty aggravating result.

Generics:
Now speaking as a policy maker, one of the ways we tried to lower the price of drugs was to encourage the availability of generic drugs. We developed the legislation known as Hatch-Waxman which tried to balance appropriate incentives for innovative drugs through an assured period of patent protection with the ability to bring generics to the market faster once that period ended.

We tried to carefully balance the incentives and rewards on both sides.

But over time, particularly as the pipe line for new drugs dried up, many companies began to exploit legal loopholes to extend the period of their monopolies on older drugs.

So we have seen that in situation after situation, the industry has acted to block generics and extend the period of time that they can continue to charge the public high prices without the competition of cheaper alternatives.

Many of those practices came to light over the last several years. These included abusing the law to gain successive 30-month delays in generic competition after the original patent on the drug had expired by last-minute filing of new, often frivolous patents on the very same drug. Another practice was the brand name company entering into collusive agreements with a generic drug manufacturer to keep all generics off the market.

These delays in competition cost consumers, the States, the Federal government and insurers billions of dollars a year.

Some of those loopholes were closed in the Medicare Modernization Act.

Not surprisingly, however, no sooner is one loophole closed than the industry appears to be finding a new one. Some brand name manufacturers are now marketing their own generic version of their drug during the 6-month period of exclusive marketing that was

supposed to be provided to encourage generics to challenge invalid patents and get on the market as soon as possible.

If the result is that generics can no longer see the reward in incurring the costs and doing the work to challenge patents, then generic competition will be significantly delayed, and consumers will be the losers.

Is it understandable that brand name companies take these actions to protect their profits?

It is if maximizing profits for the company and its shareholders is the most important goal of the company.

Now I'm not here to say that companies shouldn't make a reasonable profit. But when drug companies consistently are among the most profitable industries in this country, people are going to question whether we don't need some balance.

Because let me emphasize this point: the product you are dealing with here is not your run-of-the-mill consumer good. It is critical to people's health. That very fact is going to affect how they view your industry and its practices.

Clinical trials issue:
Now all of these points have been about price and affordability.

While I'm sure many of you disagree with the views I've put forth, I hope I can challenge you to at least consider how these factors influence the public view of the industry.

But there has recently been a focus on another issue which potentially can damage the view of the industry in even more troubling ways: that is the recent evidence that drug companies have not been fair and forthcoming with the information they make available about their products.

The issue is simply this: when clinical trials have favorable results, they are aggressively publicized. When the results are unfavorable, those studies don't see the light of day.

The result: physicians are prescribing with only part of the relevant information on the product.

The result of all of this has been tragically brought to light with the recent series of investigations and hearings into the use of antidepressants for children.

Evidence has now surfaced that use of these drugs designed to treat depression can in some cases actually increase the risk of suicide.

There are a lot of questions to be answered as to whether the FDA moved too slowly to warn physicians of the potential for an increased suicide risk.

But what makes the issue even more troubling is that the risk was associated with use of drugs where the companies' own studies failed to demonstrate effectiveness of the product. That unfavorable information was kept from the public by the manufacturers.

Indeed, there were even instances where studies which showed a negative result were reported in medical journals as though the result was positive.

Unfortunately, the case of anti-depressants in children is not an outlier. As the medical journals have warned for a long time, the pharmaceutical industry has a long history of selectively promoting positive results on its drugs, and withholding negative results.

What the anti-depressant case has brought to the fore has the potential to be very damaging to the public perception of the drug industry.

If the public begins to think that drug companies are manipulating and distorting the information physicians have access to about which drugs work and what their risks are, your loss of credibility will be enormous.

I think it was the recognition of that fact that led your trade association, PhRMA, to react to the public attention by proposing a voluntary, industry-sponsored clinical trials registry, so that companies could not be accused of withholding information on any trials, favorable or not.

I believe, however, that this proposal for a voluntary system is not sufficient to give the medical community and the public the confidence they need that the information they are receiving on trials is complete and accurate.

The very financial incentives companies have to disseminate only studies that show a positive effect for their drug is the very thing that is likely to undermine compliance with a voluntary registry of clinical trials.

We need to establish a registry by law, and require companies to participate.

I've joined with Congressman Ed Markey to introduce legislation to accomplish that. A number of our colleagues in the Senate are joining us in introducing similar legislation.

We've taken great care to establish reasonable requirements that will provide necessary information to doctors, researchers and the public, without being either unnecessarily burdensome or potentially misleading. We've been careful to confer with many interested parties, including drug companies I might note, to try to get this right.

It is my firm belief that the pharmaceutical industry itself has as much to gain by this action as patients and providers do. Restoring credibility is surely a very worthwhile result.

Ultimately, we owe Americans more information about drugs than even a clinical trial registry can provide. We must, as a society, be able to provide patients with credible judgments about how drugs compare to each other, both in comparative safety and effectiveness, and in cost-effectiveness.

When new drugs cost tens or even hundreds of times what older drugs cost, and when health care dollars are already maximally stretched, we have no choice but to insist on objective data comparing the usefulness of drugs. Yet good comparative studies are extremely rare.

That is why I support legislation charging the federal government with conducting and funding comparative studies on drugs. I would hope it would have industry support as well.

The Medicare prescription drug program:

Before I close, I want to return to where we started: the Medicare prescription drug program that will be implemented in 2006.

It is no secret that I believe the program established by the Medicare legislation pushed through by the Bush administration and the Republican leadership in the Congress is fatally flawed.

It is not the drug benefit Medicare beneficiaries want and need.

Administration by private plans:
First, beneficiaries like Medicare. The drug benefit should have been integrated directly into the program, established clearly by law and administered under uniform rules established by the Medicare program itself.

Instead we have a benefit that will be designed, within certain parameters, by private insurers and HMOs. It will vary in cost depending on where you live and what the plans in your area decide to charge.

It may indeed be hard to find an acceptable plan because of the reluctance of companies to offer a single-benefit that is sure to be utilized.

Too many choices:
Second, there will be a great deal of variety among plans.

The popular mantra at the moment is that choice is great and will make people happy. I think the evidence indicates the contrary.

Too much choice can be paralyzing. Too much information can be overwhelming.

And trying to decide what plan with what array of covered drugs will best meet an elderly or disabled person's needs can be frightening, particularly with a population that is likely to have an array of illnesses and be uncertain as to what other need for medication may be on the horizon.

The fear and confusion over the drug discount card certainly has kept enrollment down. But the stakes in the decision if you pick the wrong prescription drug insurance plan are much greater than those involved in picking the wrong discount card.

The potential for confusion and anger to overwhelm this program is very real.

Remember, each plan will set up its own formulary, establish its preferred drugs, and vary copayments to control utilization. And whatever they set up when they enroll beneficiaries in their policies, they will be free to change after a month.

Now this obviously can be a problem. Medicare, after all is a program for people who are seniors or disabled individuals. And many of those Medicare seniors are not the active and healthy 65-year old, but the frail and dependent 85-year old.

Anytime a private insurance structure is used to deliver benefits to a population which by its very nature is older and sicker than the average American means the opportunity to design the benefit to discourage enrollment by people who will use a lot and cost a lot is there.

CMS at this very time is struggling with the guidelines for how many classes of drugs plans will be required to offer. The law says there must be two choices in each class.

No one knows better than this group that the choice and availability of drugs that will be available to beneficiaries will depend on the number and breadth of classes that are established.

Certainly more classes means more likelihood of choice. Yet more classes also means potentially less ability to control costs by limiting coverage to the most cost effective alternative.

The stakes are high, because the guidelines laid out by CMS will in effect offer a safe harbor for plans. If they can show they comply, they will be protected against charges that they have designed their coverage in a way to cherry pick the most healthy Medicare beneficiaries.

It is going to be very hard to get this right.

Inadequate benefit:
All of these problems will be exacerbated by the complexity and inadequacy of the benefit. First a deductible, then some coverage, then no coverage—the so-called donut hole where the beneficiary is on their own.

People are going to be constantly bewildered about when they are covered and when they are not.

Limitation on the ability to negotiate prices:
And underlying all the dissatisfaction that this structure will bring is the perception—based on reality I might add—that it was the influence of the drug companies that kept a single Medicare structure from being adopted.

Rather than Medicare running the program and negotiating the best price for its 40 million beneficiaries, we have a law that actually prohibits the Secretary of HHS from using that power.

And that takes us full circle back to my earlier remarks.

Nobody likes to pay high prices. But when people think they are being taken advantage of and other people—or countries—are getting better deals, they are going to resent the industry that put them in this position.

Conclusion:

I know much of what I have had to say here today is not what most of the people in this room want to hear.

I know you might want to dismiss it by saying "oh, this guy is on the fringe. He probably hates all the drug companies."

Well, those of you who have followed my career know that that is not so.

I recognize the contributions of the drug industry to our health and well being.

I worked very hard with the Hatch-Waxman legislation to keep appropriate incentives for companies to continue innovation, and to reward them for it.

I authored the Orphan Drug Act. I passed the legislation that provided incentives to do research on pediatric uses of drugs. I am a dependable defender of the value of vaccines and the need to help industry continue to produce them. I authored the vaccine compensation system.

I even have been reluctant to embrace reimportation.

But the kind of manipulation of the system to maintain high prices, and the discrimination in the prices that are charged, cannot be sustained.

In the end, it is the credibility of the industry itself that will be damaged.

And that is something that all of you can change.